# CLAIMS

What is claimed is:

1. A device for detecting the presence of a ligand in a sample, comprising,

a cassette having a first and a second end, and comprising an inlet port at the first end which is in fluid communication with at least one flow channel, said flow channel comprising, in series, at least one mixing chamber, and a detection chamber delineated on at least two sides by low or non birefringent glass and in fluid communication with the at least one mixing chamber,

wherein the detection chamber is located at the second end of the cassette, and

wherein the arrangement of the outlet port, the one or more mixing chambers, and the detection chamber define a substantially linear flow path from the first end to the second end of the cassette.

2. The device according to claim 1, wherein the inlet port comprises a one-way valve.

3. The device according to claim 1, wherein the flow channel comprises a first conduit connecting the inlet port and the at least one mixing chamber, and a second conduit connecting the at least one mixing chamber and the at least one detection chamber.

4. The device according to claim 1, wherein the flow channel comprises two or more mixing chambers arranged in series, wherein the first mixing chamber is in fluid communication with the inlet port, and wherein the last mixing chamber in the series is in fluid communication with the detection chamber.

5. The device according to claim 4, wherein the flow channel comprises two or more conduits, wherein each conduit is arranged in series with the inlet port, the mixing chambers, and the detection chamber, and a conduit is situated between and in fluid communication with either the inlet port and a mixing chamber, or two or the two or more mixing chambers.

6. The device according to claim 5, wherein one or more of the conduits comprise structures that induce turbulent flow when the device is in use.

7. The device according to claim 6, wherein the structures that induce turbulent flow are selected from the group consisting of baffles, blades, ribs, bars and combinations thereof.

8. The device according to claim 7, wherein the structures that induce turbulent flow are either moving or non-moving.

9. The device according to claim 1, comprising a conduit situated between a mixing chamber and the detection chamber, wherein said conduit induces laminar flow when the device is in use.

10. The device according to claim 9, wherein the conduit has an internal diameter that is greater than the internal diameter of the immediately adjacent mixing chamber.

11. The device according to claim 4, wherein one or more of the mixing chambers comprise structures that induce turbulent flow when the device is in use

12. The device according to claim 1, wherein one or both of the low or non birefringent glass walls located in the mixing chamber has longitudinal microgrooves oriented along the axis of the cassette that bisects the first and second ends of the cassette.

13. The device according to claim 1, comprising at least one polarized filter in communication with the detection chamber and located adjacent to one wall of low or non birefringent glass.

14. The device according to claim 1, wherein the device, when in use, provides for the flow of fluid through the flow channel from the first to the second end of the cassette, wherein the flow pattern between the inlet port and the one or more mixing chambers is substantially turbulent, and wherein the flow pattern between the mixing chamber and the detection chamber is substantially laminar.

15. The device according to claim 1, wherein the cassette comprises an array of at least two flow channels.

16. The device according to claim 15, wherein the cassette comprises from two to fifty flow channels.

17. A system for detecting the presence of a ligand in a sample, comprising:

(a) the device according to claim 1, comprising at least one assay cassette; and

(b) a flow directing device in communication with the assay cassette

wherein the flow directing device, when in use, interfaces with the at least one assay

cassette to initiate and direct the flow of fluid through the at least one flow channel along a substantially linear path from the first end to the second end of the at least one assay cassette.

18. The system according to claim 17, wherein the at least one assay cassette comprises an array of two or more flow channels.

19. The system according to claim 18, wherein each of the two or more flow channels of the at least one assay cassette comprises at least one polarized filter in communication with a first side the detection chamber and located adjacent to one wall of low or non birefringent glass, and at least one polarized filter in communication with a second side of the detection chamber and located adjacent to one wall of low or non birefringent glass.

20 The system according to claim 19, comprising, in communication with the second side of the detection chamber, a reader which is capable of detecting light transmission through the detection chamber from a light source applied to the first side of the detection chamber.

21. The system according to claim 17, wherein the flow directing device is selected from a roller, a syringe and a pump.

22. The system according to claim 21, wherein the flow directing device is a roller, which, in use, contacts the first end of the at least one assay cassette and rolls over the length of the array of channels, thereby providing pressure that induces fluid flow along the length of the cassette toward the second end of the cassette.

23. A flow channel module for use in a device for detecting the presence of a ligand in a sample, comprising:

> a first chamber comprising in its interior a composition which exhibits specificity for a ligand, selected from the group consisting of a microparticle and a receptor; and
>
> a second chamber comprising in its interior a liquid crystalline material,

wherein the first and second chambers are in fluid communication with each other.

24. The flow channel module according to claim 23, wherein the first chamber comprises in its interior a receptor which exhibits specificity for a ligand, and wherein the flow channel module comprises a third chamber that is in fluid communication with either or both

said first and second chambers, and said third chamber comprises in its interior a microparticle which exhibits specificity for the receptor.

25. The flow channel module according to claim 23, comprising a detection chamber which is delineated on at least two opposing sides by low or non birefringent glass, and is in fluid communication with at least one of chambers one and two, wherein one or both of the walls of low or non birefringent glass has longitudinal microgrooves oriented along the axis of the cassette that bisects the first and second ends of the cassette.

26. The flow channel module according to claim 25, wherein the flow channel module has a first end and a second end, and comprises at its first end an inlet port that is in fluid communication with at least one of chambers one and two.

27. The flow channel module according to claim 26, wherein the chambers are arranged in series, and wherein the inlet port is in fluid communication with the first chamber, the first chamber is in fluid communication with the second chamber, and the second chamber is in fluid communication with the detection chamber which is located at the end of the flow channel module.

28. The flow channel module according to claim 27, wherein the first chamber comprises in its interior a receptor which exhibits specificity for a ligand, and wherein the flow channel module comprises a third chamber that is situated between and in fluid communication with either the inlet port and the first chamber, or the first chamber and the second chamber, said third chamber comprising in its interior a microparticle which exhibits specificity for the receptor.

29. The flow channel module according to claim 27, comprising conduits between each of said chambers.

30. The flow channel module according to either of claims 22 or 28, wherein the conduits between all or any of the inlet port and the first, second and third chambers comprise structures that induce turbulent flow when the device is in use.

31. The device according to claim 30, wherein the structures that induce turbulent flow are selected from the group consisting of baffles, blades, ribs, bars and combinations thereof.

32. The device according to claim 31, wherein the structures that induce turbulent flow are either moving or non-moving.

33. The device according to claim 29, comprising a conduit situated between the second chamber and the detection chamber, wherein said conduit induces laminar flow when the device is in use.

34. A reader module for use in a device for detecting the presence of a ligand in a sample, comprising;

a housing adapted to accept one or more flow channel modules according to claim 25,

a flow directing device adapted to interface with the one or more flow channel modules,

at least one polarized filter adapted to interface with a first side of the detection chambers of the one or more flow channel modules,

at least one polarized filter adapted to interface with a second side of the detection chambers of the one or more flow channel modules, and

a reader which is adapted to interface with the second side of the detection chamber of the one or more flow channels and is capable of detecting light transmission through the detection chambers,

wherein the polarized filters interfaced on the first and second sides of the detection chambers are oriented at 90° relative to each other, and wherein one of the polarized filters is aligned with the longitudinal microgrooves,

wherein the flow directing device, when in use, interfaces with the one or more flow channel modules to direct the flow of fluid through the one or more flow channel modules along a substantially linear path from the first end to the second end of one or more flow channel modules, and

wherein said reader, when in use, detects the transmission of light through the detection chamber of the one or more flow channel modules upon the application of light to the first side of the detection chamber.

35. The system according to claim 34, wherein the flow directing device is selected from a roller, a syringe and a pump.

35. A method for detecting the presence of a ligand in a sample, comprising,

introducing a sample suspected of containing the ligand in to a flow channel comprising a first chamber comprising in its interior a receptor composition which exhibits specificity for the ligand, wherein the composition is selected from the group consisting of a microparticle and a receptor,

mixing said sample and said receptor composition by means of turbulent flow,

transmitting said sample and receptor mixture along the flow channel to a second chamber comprising in its interior a liquid crystalline material,

mixing said sample and receptor mixture by means of turbulent flow,

transmitting said sample, receptor and liquid crystalline mixture by laminar flow along the flow channel to a detection chamber which is delineated on at least two sides by low or non birefringent glass,

examining the contents of the detection chamber for the presence of inclusion bodies comprised of aggregates of the ligand and receptor,

wherein the polarized filters interfaced on the first and second sides of the detection chambers are oriented at 90° relative to each other, and wherein one of the polarized filters is aligned with the longitudinal microgrooves,

wherein examination is by application of a light source to a first side of the detection chamber and detection of transmittance of light by a reader situated at a second side of the detection chamber which is opposite said first side,

and wherein no transmittance of light through the detection chamber is indicative of the absence of inclusion bodies, and transmittance of light through the detection chamber is indicative of the presence of inclusion bodies,

and wherein the presence of inclusion bodies is indicative of the presence of the ligand in the sample.

36. The method according to claim 35, wherein the sample is washed and filtered prior to introduction to the flow channel.

37. The method according to claim 35, wherein the sample is diluted or concentrated

prior to introduction to the flow channel.

38. The method according to claim 35, wherein the sample is analyzed using an array of flow channels.

39. The method according to claim 38, comprising at least one negative control which comprises one or more flow channels comprising a first chamber comprising in its interior a receptor composition which does not exhibit specificity for the ligand.

40. The method according to claim 38, comprising at least one positive control which is run in parallel, wherein one or more control flow channels are provided which do not receive introduced sample, each control flow channel comprising one or more control chambers comprising the ligand and a receptor which exhibits specificity for the ligand,

mixing said ligand and said receptor by means of turbulent flow,

transmitting said ligand and receptor mixture along the flow channel to a chamber comprising in its interior a liquid crystalline material,

mixing said ligand, receptor and liquid crystalline mixture by means of turbulent flow,

transmitting by laminar flow said ligand, receptor and liquid crystalline mixture along the flow channel to a detection chamber which is delineated on at least two sides by low or non birefringent glass,

examining the contents of the detection chamber for the presence of inclusion bodies comprised of aggregates of the ligand and receptor,

wherein examination is by application of a light source to a first side of the detection chamber and detection of transmittance of light by a reader situated at a second side of the detection chamber which is opposite said first side,

and wherein no transmittance of light through the detection chamber is indicative of the absence of inclusion bodies, and transmittance of light through the detection chamber is indicative of the presence of inclusion bodies,

and wherein the absence of inclusion bodies is indicative of a failure of the assay, and presence of inclusion bodies is indicative that the assay is successful.